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PATENT

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UTILITY PATENT APPLICATION TRANSMITTAL

Attorney Docket No.: P8769
Express Mail No.: EL191394705US

First Named Inventor or Application Identifier: Richard L. Weiner
Title: Peripheral Nerve Stimulation Method

CERTIFICATE UNDER 37 CFR SECTION 1.10: I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service, in an envelope address "EXPRESS EL191394705US addressed to Box Patent Application, Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this May 22, 2000.

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_ Continuation _ Divisional _ Continuation-in-Part of prior application no. __.

_ Amend the specification by inserting before the first line the sentence: This application is a _ Continuation _ Divisional _ Continuation-in-Part of application number _ filed _.

_ Cancel in this application original claims _ of the prior application before calculating the filing fee. (At least one of the original independent claims must be retained for filing purposes.)

_ The prior application is assigned of record to Medtronic, Inc.

_ The Power of Attorney in the prior application is to: _.

X This application claims the benefit of U.S. Provisional Application(s) Serial No.60/136,690 filed May 29, 1999.

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FEE CALCULATION

	No. Of Claims Filed	Claims Included in Base Fee	No. Of Extra Claims	Rate	Fee
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Multiple Dependent Claim(s)		0 =		+ $ 260	
Basic Filing Fee			0		$690.00
				TOTAL	**$1,404.00**

X Charge Deposit Account No. 13-2546 the sum of $1,404.00 (Filing Fee) and $ for Assignment recordation fee for a total of **$1,404.00**

X The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-2546. A duplicate of this transmittal is enclosed.

May 22, 2000
Date

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PATENT
ATTORNEY DOCKET: P-8769

APPLICATION FOR UNITED STATES LETTERS PATENT

for

PERIPHERAL NERVE STIMULATION METHOD

by

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PERIPHERAL NERVE STIMULATION METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a method for subcutaneously electrically stimulating peripheral nerves and in a particular embodiment relates to a method for subcutaneously electrically stimulating one or more occipital peripheral nerve to treat occipital neuralgia.

2. Description of Related Art

Peripheral nerves are nerves in the body other than the nerves of the brain or spinal cord. Peripheral nerve injury may result in the development of chronic intractable pain. Some patients prove unresponsive to conservative pain management techniques. Peripheral Nerve Stimulation (PNS) has developed as a successful therapy for pain management when the pain is known to result from a specific nerve. PNS is based in part on the Melzack-Wall gate control theory of pain. Sweet and Wespic first used electrical stimulation of peripheral nerves in the 1960s to mask the sensation of pain with a tingling sensation (paresthesia) caused by the electrical stimulation. Subsequent refinements in the technology, surgical technique and patient selection have led to improved long term results.

PNS is an accepted alternative for those patients who have failed more conservative pain management therapies. Clinical experience has shown that when applied to appropriate patients by trained practitioners, PNS can reduce pain, reduce narcotic intake to manage pain and improve the patient's activity levels and their quality of life. PNS has been recognized to have the following desirable characteristics:

- The surgical procedure is relatively simple.

- PNS is nondestructive. No known permanent surgical or chemical interruption of nerve pathways occurs.
- PNS is reversible. If the patient does not benefit, the device can be turned off or removed. There are no known long-lasting medical or surgical side effects.
- Patients can be tested for response prior to implant of the complete system.

Occipital nerves 2, 4 and 6 (Figure 1) are peripheral nerves that exit the spinal cord at the C2 level of the cervical vertebrae and extend upward generally along the back and back-sides of the head. The lesser occipital nerve 2 extends upward and toward the sides of the head. The greater occipital nerve 4 extends upward toward the top of the head. The third occipital nerve 6 extends from near the neck around the back of the head toward the ear. Because of the location where the occipital nerves leave the spinal cord, the occipital nerves pass from the spinal column through muscle and fascia to the scalp.

Occipital neuralgia is a condition characterized by paroxysms of pain occurring within the distribution of the greater and/or lesser occipital nerves. Occipital neuralgia has been described as a "jabbing" pain in the area of the greater or lesser occipital nerve. The pain may radiate from the back or sides of the head toward the top or front of the head. Patients will vary in their reporting of this pain. It has been characterized in the medical literature as a unilateral or bilateral throbbing pain that frequently radiates to the forehead and to the frontal region (Stechison and Mullin, 1992) or as a lancinating pain extending from the suboccipital region up to the top of the head. The pain is less often described as including or consisting of a dull aching" (Sulfaro and Gobetti, 1995). Occipital neuralgia is often accompanied by diminished sensation and sometimes extreme localized tenderness over the applicable nerve.

Though known causes of occipital neuralgia include closed head injury, direct occipital nerve trauma, neuroma formation or upper cervical root compression (spondylosis or ligamentous hypertrophy), most patients have no demonstrable lesion. An anesthetic block of the greater occipital nerve can be used to confirm the diagnosis of occipital neuralgia (Khun, et al., 1997).

Traditional treatment options for intractable occipital nerve pain that has proven to be resistant to medications usually involve chemical, thermal or surgical ablation procedures following diagnostic local anesthetic blockade. Surgical approaches include neurolysis or nerve sectioning of either the occipital nerve in the occipital scalp or at the upper cervical dorsal root exit zone (extradural). Forammal decompression of C2 roots as well as C2 ganglionectomy have also been effective in reported cases.

Many patients with occipital neuralgia do not favorably respond to these medical treatments. Therefore, there is a need for an additional effective treatment of occipital neuralgia.

SUMMARY OF THE INVENTION

A method for treating pain by subcutaneous electrical stimulation is disclosed. A lead is placed subcutaneously over (superior to) a peripheral nerve that is causing pain. The nerve is electrically stimulated to cause paresthesia. As a result, the pain is masked. The method of the invention encompasses subcutaneous placement of an electrical lead near any peripheral nerve causing pain and subsequent electrical stimulation of the nerve to cause paresthesia.

In particular, a method for treating intractable occipital neuralgia using percutaneous peripheral nerve electrostimulation techniques is disclosed. The method involves a subcutaneous electrode placement at the level of C1 transversely across the base of the

occipital nerve trunk and subsequent electrical stimulation of the occipital nerve trunk. This stimulation produces paresthesia and pain relief covering the regions of occipital nerve pain.

It is therefore an object of the invention to provide a method for subcutaneously electrically stimulating nerves causing pain to create paresthesia.

It is another object of the invention to provide a method for percutaneously placing leads subcutaneously to create paresthesia.

These and other object of the invention will be clear from the following detailed description of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic view of the occipital nerves.

Figure 2 is a schematic view of the hardware used to practice the invention of the present invention.

Figure 3 is a perspective view of a screener device and a screening lead.

Figure 4 is a top view of a permanent lead.

Figure 5 is a perspective view of an implantable pulse generator (IPG).

Figure 6 is a perspective view of an RF system receiver and an RF system transmitter.

Figure 7 is a top view of an introducer needle curved to facilitate placement of the permanent lead to treat occipital neuralgia.

Figure 8 is a schematic view of the entry site used to implant a screening lead or a permanent lead for treating occipital neuralgia.

Figure 9 is a schematic view of the placement of the introducer needle prior to placing the screening lead.

Figure 10 is a schematic view of the placement of the introducer needle with the screening lead being inserted into the introducer needle.

Figure 11 is a schematic view of dual leads placed to treat bi-lateral pain.

Figure 12 is a perspective view of a patient prior to being implanted with a permanent lead.

Figure 13 is a schematic view of the placement of the introducer needle prior to placing the permanent lead.

Figure 14 is a schematic view of the placement of the introducer needle with the permanent lead being inserted into the introducer needle.

Figure 15 is a schematic view of the location of the subcutaneous pocket for housing the loop of the permanent lead and the lead anchor.

Figure 16 is a perspective view of a human torso and arm showing the location of the leads for two embodiments of the invention.

Figure 17 is a perspective view of a human torso and arm showing the exit sites of the leads and preferred location for an IPG for the method of Figure 16.

Figure 18 is a perspective view of a human leg showing the location of a lead and IPG for an embodiment of the invention.

Figure 19 is a perspective view of a human leg showing the location of a lead and IPG for another embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention comprises a method of stimulating peripheral nerves. The method is preferentially accomplished in two stages: a test implantation and screening stage and a permanent implantation of a lead and electrical stimulation system stage. The invention

contemplates using, as shown in Figure 2, a screening lead 10 (shown in detail in Figure 3), a screener device 12 (also shown in detail in Figure 3), a permanent lead 14 (shown in detail in Figure 4) and either an implanted pulse generator (IPG) 16 (shown in detail in Figure 5) or an implanted RF system receiver 18 and its corresponding RF system transmitter 20 (shown in detail in Figure 6).

The screening lead 10 and permanent lead 14 are preferably percutaneous leads chosen from the Pisces-Quad® family of quadripolar leads. Screener device 12 is preferably a Model 3625 Screener or a Model 3628 DualScreen® Screener. IPG 16 is preferably an Itrel® IPG. RF system receiver 18 and RF system transmitter 20 are both preferably part of an RF stimulation system such as the X-trell® or Matrix® RF Stimulation Systems. Screening lead 10, permanent lead 14, screener device 12, IPG 16, RF system receiver 18 and RF transmitter 20 are all available from Medtronic, Inc. of Minneapolis, Minnesota.

The method for treating pain due to peripheral nerves involves subcutaneous placement of a permanent lead 14 transversely across the peripheral nerve that is causing the pain. This peripheral nerve is subsequently electrically stimulated to cause paresthesia of the painful area. The method also preferably involves placement of a screening lead 10 and subsequent test electrical stimulation prior to placing the permanent lead 14. Although the method preferably involves placing both a screening lead 10 and then a permanent lead 14, the method also includes implanting just the permanent lead 14 as will be described in detail hereafter. For illustration purposes, the method for treating pain due to peripheral nerves will be described with reference to treating occipital neuralgia by electrically stimulating the occipital nerves.

One key to the technical success of this invention is the accurate placement of the permanent lead 14. Because of the importance of accurate placement of the permanent lead

14, accurate placement of permanent lead 14 is facilitated by the placement of the screening lead 10 and the subsequent test electrical stimulation. The steps in the invention to percutaneously place a screening lead 10 to treat occipital neuralgia will now be described in detail. These steps are given as the preferred method of implementing the invention for most patients. It is recognized, however, that the skilled physician will adapt the method described herein using his or her professional skill and judgment to the particular circumstances of a particular patient. Further, although the method of treating pain described in detail herein is specifically directed to treating occipital neuralgia, unless otherwise specifically directed, any reference to the occipital nerve or occipital neuralgia refers as well to any peripheral nerve or neuralgias corresponding to a peripheral nerve, respectively.

The first step of the test implantation and screening stage is the implantation of a screening lead 10. The method involves subcutaneous placement of a screening lead 10 in the fascia 34 above (superior to) the occipital nerve causing pain and proximal to the level of detected pain. The first step in locating the area to implant the screening lead 10 is to palpate the area of pain to identify the specific nerve that is causing the pain. If it is confirmed that an occipital nerve is causing the pain and the specific occipital nerve has been identified, an introducer needle 22 is used to place the screening lead 10.

The preferred embodiment for the introducer needle 22 is a Touhy needle. As shown in Figure 7, the introducer needle 22 has a terminal end 24 that has a beveled edge 26 and a proximal end 28 that includes a hub 30. Beveled edge 26 is a sharp edge that allows the terminal end 24 to be pushed through tissue. Hub 30 allows the physician to manipulate the introducer needle 22. Hub 30 also has a notch 32 that is aligned with the beveled edge 26 to indicate the orientation of beveled edge 26 to the hub 30 by tactile sensation.

The introducer needle 22 is then subcutaneously placed in the fascia 34 above (superior to) the nerve 36 that is causing the pain. In the case of treating occipital neuralgia, the introducer needle 22 is placed in the fascia 34 above (superior to) the occipital nerve that is causing the pain. Fascia 34 is a sheet of fibrous tissue that envelops the body under the skin and also encloses the muscles. In the described method, the introducer needle 22 will be introduced into the fascia 34 so that the introducer needle will be between the patient's skin and muscle. The nerve causing the pain will be located within or under the musculature. In the case of treating occipital neuralgia, the introducer needle 22 will be introduced into the fascia 34 so that the introducer needle will be between the patient's skin and the occipital nerve.

The introducer needle 22 is preferably introduced through a small stab wound "A" at the needle entry site (Figure 8). Rapid needle insertion is preferably used. This technique usually obviates the need for even a short acting general anesthetic.

The introducer needle 22 is moved through the fascia 34 to a position over the occipital nerve that is causing the pain (Figure 9). When the introducer needle 22 is in position above the occipital nerve, the screening lead 10 is passed through the introducer needle 22 (Figure 10) until the screening lead 10 is also in position above the occipital nerve causing the pain. Then, the introducer needle 22 is removed leaving the screening lead 10 in place above the occipital nerve.

Single or dual quadripolar as well as single or dual octapolar screening leads 10 may be used depending on whether the pain is unilateral (on one side of the body only) or bilateral (on both sides of the body). Where the pain is bilateral and two screening leads 10 are used (Figure 11), each screening lead 10 will be placed as described above.

Following placement of the screening lead 10 by the introducer needle 22, the screening lead 10 is connected to the screening device 12, as is well understood in the art. With the screening lead 10 in place as described above and the screening lead 10 connected to the screening device 12, the patient is electrically stimulated by the screening lead 10 and screener device 12 to evaluate the screening lead 10 position and to develop optimal stimulation parameters. Stimulation is applied using the screener device 12 to select various electrode combinations, enabling the patient to report stimulation location, intensity and overall sensation. This allows the physician to test the stimulation and determine optimum stimulation parameters prior to permanently implanting the permanent lead 14 and the source of electrical stimulation pulses, either the IPG 16 or the RF system receiver 18. The effect of this stimulation is determined and the parameters of stimulation adjusted for optimal pain relief. It is preferred that the patient be awake and alert so that the patient will provide verbal feedback regarding paresthesia coverage of the painful area to assist in determining the optimum stimulation parameter settings.

The following have been found to be typical ranges for stimulation parameters for screening by the screener device 12 and the screening lead 10 to optimize paresthesia levels for pain coverage. These parameters can vary from patient to patient and may be outside the ranges given here. Never-the-less, these representative values are given for the purpose of illustrating the invention and not for the purpose of limiting the invention. Values for these parameters may be higher or lower than the values shown.

Amplitude:	0.5 - 4.0 volts
Pulse Width:	90 – 200 μsec
Rate:	50 - 400 Hz

If the patient reports muscle contractions (grabbing sensation) or burning, this usually indicates that the screening lead 10 is located too deep (anterior) in the subcutaneous tissue. It may also indicate that the screening lead 10 is not positioned correctly above (superior to) the nerve. It may be necessary to remove and reposition the screening lead 10. If adjustment of screening lead 10 is necessary, the screener device 12 is removed from the screening lead 10. Then, the position of the screening lead 10 is adjusted and stimulation is tested again for optimal pain relief. Adjusting the position of the screening lead 10 may mean removing the screening lead 10 and re-implanting the screening lead 10 according to the technique described above.

After good paresthesia coverage is obtained by manipulating the parameters of stimulation applied through screening lead 10, percutaneous testing wires can be externalized for the test stimulation period as is well understood in the art. This period is used to evaluate the patient's response to stimulation before complete implantation of all system components.

Alternately, once satisfactory paresthesia is confirmed, the screener device 12 may be removed from the screening lead 10 and a source of electrical stimulation pulses such as the IPG 16 or RF system receiver 18 is immediately implanted and attached to the screening lead 10. Hence, screening lead 10 in this embodiment becomes permanent lead 14. However, it is preferred that the patient use the implanted screening lead 10 and screener system 12 for several days prior to implanting a permanent stimulation system.

Once the screening lead 10 has been appropriately positioned and tested, if satisfactory results are obtained, the method should proceed to the "permanent implantation of a lead and electrical stimulation system" stage. The steps in the invention to permanently implant a stimulation system will now be described in detail in connection with the treatment of occipital

neuralgia. As mentioned above, it is possible to implant a source of electrical stimulation pulses such as the IPG 16 or RF system receiver 18 and attached it directly to the screening lead 10 so that screening lead 10 becomes the permanent lead 14. However, the preferred embodiment of the invention contemplates removing the screening lead 10 and replacing it with a permanent lead 14.

After it has been determined that the patient is receptive to pain relief from electrically stimulating the peripheral nerve causing the pain and the paresthesia associated with the electrical stimulation has been maximized, the screener device 12 is disconnected from the stimulation lead 10 and the screening lead 10 is removed. The patient is then prepared for placement of the permanent lead 14 and the implanted pulse generator (IPG) 16 or implanted RF system receiver 18. The purpose of the "permanent implantation of a lead and electrical stimulation system" stage is to internalize (that is, implant) the permanent lead 14 and either the IPG 16 or the RF system receiver 18. Therefore, this stage includes implanting the permanent lead 14, neurostimulator (either IPG 16 or RF system receiver 18) and any extension sometimes used to connect permanent lead 14 and either IPG 16 or RF system receiver 18 as is well understood in the art.

As stated above, one key to the technical success of this invention is the accurate placement of the permanent lead 14. It is therefore crucial to the success of the invention to have a lead placement for the permanent lead 14 that results in paresthesia that covers the patient's painful area. Therefore, lead placement is preferably determined using patient feedback during intraoperative testing of the efficacy of the permanent lead 14 placement and the stimulation parameters. Performing implantation of the permanent lead 14 under local anesthetic allows for this feedback.

A local anesthetic is preferably used in the area of the introducer needle 22 entry site to ensure the patient is alert and able to respond during the procedure. To help the patient relax, sedatives are also preferably administered intravenously. Prophylactic antibiotics can also be administered intravenously for protection from postoperative infection. As a result, the patient is preferably awake and alert during the placement of the permanent lead 14 and the subsequent test stimulation.

Where treating occipital neuralgia, the patient is preferably placed in a lateral position, or in a prone position with the head to the side, on a radiolucent table (Figure 12). The patient is prepared and draped according to standard surgical procedure. Fluoroscopy is used to identify the location of the C1 vertebra. The location and midline of the C1 vertebra is marked on the patient's skin with a sterile marker.

A Touhy needle is preferably used as an introducer needle 22 to introduce permanent lead 14. The introducer needle 22 includes a stylet 42. The introducer needle 22 is manually gently curved by the physician to conform to the contour of the patient's body above the peripheral nerve to facilitate placement of the permanent lead 14. Where the peripheral nerve is the occipital nerve, the introducer needle 22 is manually gently curved by the physician to conform to the contour of the patient's neck (Figure 7) to facilitate placement of the permanent lead 14.

A small stab wound "A" is made at the needle entry site (Figure 8) at the C1 level. Using local anesthesia, a 2 cm. vertical skin incision is made in the patient's neck lateral to the midline of the spine at the level of C1. The introducer needle 22 is introduced into the subcutaneous tissue, superficial to the fascia 34 and muscle layer but below the skin, without

further dissection across the trunk of the occipital nerves. These nerves are located within the cervical musculature and overlying fascia 34.

The physician then advances the introducer needle 22 transversely from the lateral incision point to and across the midline of the spine under fluoroscopic observation to the appropriate location above the trunk of the occipital nerve (Figure 13). The beveled edge 26 of the introducer needle 22 should face toward the front of the body (anterior). The orientation of the beveled edge 26 can be verified by referring to the notch 32 on the needle hub 30 of the introducer needle 22.

The curve of the introducer needle 22 may be checked, if desired, by the physician by removing and re-inserting the needle stylet 42. A useful, curved introducer needle 22 is ensured if it is easy to remove and reinsert the stylet 42 within the introducer needle 22. If desired, an additional check can be made by removing the stylet 42, then carefully inserting the permanent lead 14 through the introducer needle 22 to just beyond the beveled edge 26 of the introducer needle 22. If the curvature of the introducer needle 22 is correct, the permanent lead 14 should pass easily to just beyond the beveled edge 26 of the introducer needle 22. The permanent lead 14 is then removed and the stylet 42 re-inserted into the introducer needle 22.

Once the desired position has been reached, the stylet 42 is removed from the introducer needle 22. The permanent lead 14 is slowly inserted through the introducer needle 22 until the distal tip 36 of the permanent lead 14 just exits the introducer needle 22 (Figure 14). Then, the introducer needle 22 is carefully removed over the permanent lead 14. The permanent lead 14's placement is verified with fluoroscopy. Alternately, the introducer needle 22 can be partially removed. This allows the electrode contacts on the permanent lead 14 to be exposed while facilitating introducer needle 22 reinsertion if repositioning of the permanent

lead 14 is needed. Fluoroscopy is used to ensure that all electrodes of the permanent lead 14 are exposed. If necessary, the introducer needle 22 may be adjusted to move the permanent lead 14 to a location where the permanent lead 14 will optimally stimulate the targeted occipital nerve(s).

If more than one permanent lead 14 is to be implanted, for example, on each side of the midline to treat bilateral pain, the procedure described above is repeated for each such permanent lead 14.

Following placement of the permanent lead 14 by the introducer needle 22, the permanent lead 14 is again connected to the screening device 12, as is well understood in the art. This allows the physician to test the stimulation and confirm that paresthesia is obtained with the placement of the permanent lead 14 prior to permanently implanting the IPG 16 or the RF system receiver 18. Since the patient is preferably awake and alert, the patient will provide verbal feedback regarding paresthesia coverage of the painful area to assess the placement of the permanent lead 14.

If the patient reports muscle contractions (grabbing sensation) or burning, this usually indicates that the electrodes on the permanent lead 14 are too deep (anterior) in the subcutaneous tissue. It may also indicate that the electrodes are significantly above or below the C1 landmark. It may be necessary to remove and reposition the permanent lead 14. If adjustment of permanent lead 14 is necessary, the screener device 12 is removed from the permanent lead 14. Then, the position of the permanent lead 14 is adjusted and stimulation is tested again.

After good paresthesia coverage is obtained, the screener device 12 is removed from the permanent lead 14. It is now possible to implant the source of electrical stimulation pulses

such as the IPG 16 or RF system receiver 18 and any extension sometimes used to connect permanent lead 14 and either IPG 16 or RF system receiver 18 as is well understood in the art. Internalization of the neurostimulation system for occipital nerve stimulation preferably follows the protocol used for other Peripheral Nerve Stimulation (PNS) indications as is well understood in the art. Basically, the procedure involves creating a subcutaneous pocket 24 in tissue (Figure 15), anchoring the permanent lead 14, implanting the IPG 16 or RF system 18, tunneling the permanent lead 14 and connecting the permanent lead 14 to the IPG 16 or RF system 18 as is well understood in the art.

The following have been found to be typical ranges for stimulation parameters applied to the permanent lead 14 to obtain optimum paresthesia levels for pain coverage to treat occipital neuralgia. These values can vary from patient to patient and may be outside the ranges given here. Never-the-less, these representative values are given for the purpose of illustrating the invention and not for the purpose of limiting the invention. Again, values for these parameters may be higher or lower than the values shown.

Amplitude:	0.5 - 4.0 volts
Pulse Width:	90 – 200 μsec
Rate:	50 - 400 Hz

These steps are given as the preferred method of implementing the invention for most patients. It is recognized, however, that the skilled physician will adapt the method described herein using his or her professional skill and judgment to the particular circumstances of a particular patient.

A specific example of percutaneous nerve stimulation has been given for treating occipital neuralgia. Although the method of treating occipital neuralgia has been described in

detail, the steps described can be adapted to treating other peripheral nerve applications as medical judgment and necessity require. Examples of other applications for the described subcutaneous PNS technique include peripheral nerves in the head and neck, trunk and limbs. Examples of neuralgias in the head and neck that can be treated by stimulating peripheral nerves include, but are not limited to, post herpetic neuralgia, chronic deafferentation pain, chronic peripheral nerve pain, post craniotomy pain and incisional pain. For post herpetic neuralgia, the permanent lead 14 should preferably be placed in the vicinity of the supraorbital nerve in the forehead area. For chronic deafferentation pain, the permanent lead 14 should preferably be placed subcutaneously in the vicinity of the deafferentation pain. For chronic peripheral nerve pain, the permanent lead 14 should preferably be placed proximal to any peripheral nerve throughout the body. For chronic post craniotomy pain, the permanent lead 14 should preferably be placed in the region of the craniotomy incision.

Examples of neuralgias in the trunk that can be treated by stimulating peripheral nerves include, but are not limited to, clunial nerve pain, post herniorrhapy pain, localized low back or other spine pain and incisional neuroma pain. For clunial nerve pain, the permanent lead 14 should preferably be placed over the clunial nerve in the buttock area. For post herniorrhapy pain, the permanent lead 14 should preferably be placed subcutaneously in the region of the iliolinguinal nerve. For localized low back or other spine pain, the permanent lead 14 should preferably be placed in the vicinity of the localized area of pain. For incisional neuroma pain, the permanent lead 14 should preferably be subcutaneously placed in the region of the incisional neuroma.

Examples of neuralgias in the limbs that can be treated by stimulating peripheral nerves include, but are not limited to, stump neuroma pain, incisional scar pain, deafferention pain and

chronic peripheral nerve pain as for example with the median nerve or ulnar nerve. For stump neuroma pain, the permanent lead 14 should preferably be subcutaneously placed in the region of the neuroma. For incisional scar pain, the permanent lead 14 should preferably be subcutaneously placed in the region of the incision. For chronic peripheral nerve pain of the medial nerve or ulnar nerve, the permanent lead 14 should preferably be placed over the medial nerve 38 or ulnar nerve 40, respectively, as shown in Figure 16. Here, the technique described above is applied to the placement of screening lead 10 and permanent lead 14 with the leads 10, 14 located above (superior to) the desired peripheral nerve through medial nerve incision site 42 and ulnar nerve incision site 44, respectively. Once the permanent lead 14 is in place, the IPG 16 or RF system receiver 18 is implanted as is well understood in the art (Figure 17) and connected to the permanent lead 14.

Figures 18 shows the placement of a permanent lead 14 next to the sciatic nerve 46 in the leg. Permanent lead 14 is implanted as described above through the sciatic nerve incision site 48. Placement of permanent lead 14 and the subsequent electrical stimulation of the sciatic nerve 46 could treat neuromas or chronic pain emanating from this peripheral nerve.

Further, Figure 19 shows the placement of a permanent lead 14 next to a peripheral nerve 48 in the ankle, foot or other localized are of pain. Permanent lead 14 is implanted as described above through a peripheral nerve incision site 50. Placement of permanent lead 14 and the subsequent electrical stimulation of the affected peripheral nerve 44 could also treat neuromas in or around this peripheral nerve and also chronic pain arising from this nerve.

The examples of the method of the invention shown in Figures 16 – 19 have been given to illustrate examples of peripheral nerves to which the present method could apply. The application of the present invention to other peripheral nerves with their corresponding

maladies and neuromas will occur to those skilled in the art. Conversely, once neurological maladies or neuromas and their corresponding peripheral nerves have been identified, as will also occur to those skilled in the art, the present invention may be used to treat such maladies or neuromas. It is clear that those skilled in the art will be able to practice the invention described above as applied to any peripheral nerve or to treat any particular neuroma by applying the disclosed method to its corresponding peripheral nerve.

The description contained herein is intended to be illustrative and not exhaustive. Many variations and alternatives will occur to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

I claim:

1. A method of stimulating a peripheral nerve to treat pain emanating from the peripheral nerve, the method comprising the steps of:

placing a lead near a peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area.

2. The method of claim 1 wherein the step of placing a lead includes the step of placing a lead across the peripheral nerve that is causing pain.

3. The method of claim 2 wherein the step of step of placing a lead across the peripheral nerve that is causing pain includes the step of subcutaneously placing a lead across the peripheral nerve that is causing pain.

4. The method of claim 3 wherein the step of subcutaneously placing a lead includes the step of subcutaneously placing a lead in the fascia superior to the peripheral nerve.

5. The method of claim 4 wherein the step of subcutaneously placing a lead in the fascia superior to the peripheral nerve includes the step of subcutaneously placing a lead in the fascia superior to the peripheral nerve proximal to the level of detected pain.

6. The method of claim 1 wherein the step of placing a lead includes the step of subcutaneously placing a lead near the peripheral nerve that is causing pain.

7. The method of claim 6 wherein the step of subcutaneously placing a lead includes the step of subcutaneously placing a lead in the fascia superior to the peripheral nerve.

8. The method of claim 7 wherein the step of subcutaneously placing a lead in the fascia superior to the peripheral nerve includes the step of subcutaneously placing a lead in the fascia superior to the peripheral nerve proximal to the level of detected pain.

9. The method of claim 1 further comprising the step of initially palpating the area of pain to identify the specific peripheral nerve that is causing the pain.

10. The method of claim 1 wherein the step of placing a lead includes the steps of:

providing an introducer needle;

subcutaneously placing the introducer needle in the fascia superior to the peripheral nerve that is causing pain.

11. The method of claim 10 wherein the step of placing a lead further includes the step of passing, when the introducer needle is in position above the peripheral nerve, the lead through the introducer needle until the lead is also in position above the peripheral nerve causing the pain.

12. The method of claim 11 further comprising the step of removing, after passing the lead through the introducer needle until the lead is also in position above the peripheral nerve causing the pain, the introducer needle leaving the lead in place above the peripheral nerve.

13. The method of claim 10 wherein the step of subcutaneously placing the introducer needle in the fascia superior to the peripheral nerve that is causing pain. includes the step of curving the introducer needle to conform to the contour of the patient's body superior to the peripheral nerve.

14. The method of claim 1 wherein the step of placing a lead includes the step of placing dual leads.

15. The method of claim 14 further comprising the step of connecting the lead to a screening device.

16. The method of claim 15 further comprising the step of performing test electrical stimulation with the lead.

17. The method of claim 16 wherein the step of performing test electrical stimulation with the lead includes the step of electrically stimulating the patient by the lead and screener device to evaluate the lead position.

18. The method of claim 16 wherein the step of performing test electrical stimulation with the lead includes the step of electrically stimulating the patient by the lead and screener device to develop optimal stimulation parameters.

19. The method of claim 16 further comprising the step of receiving verbal feedback from the patient regarding paresthesia coverage of the effects of the electrical stimulation by the lead.

20. The method of claim 16 wherein the step of performing test electrical stimulation with the lead includes the step of electrically stimulating the patient with an electrical signal having an amplitude between about 0.5 to about 4.0 volts.

21. The method of claim 16 wherein the step of performing test electrical stimulation with the lead includes the step of electrically stimulating the patient with an electrical signal having a rate between about 50 Hz. to about 400 Hz.

22. The method of claim 16 wherein the step of electrically stimulating the patient with an electrical signal having a rate between about 50 Hz. to about 400 Hz. includes the step of electrically stimulating the patient with an electrical signal having a pulse width between about 90 μsec to about 200 μsec.

23. The method of claim 1 further comprising the steps of:

implanting an implantable pulse generator; and

electrically connecting the implantable pulse generator to the lead.

24. The method of claim 1 further comprising the steps of:

implanting a RF system receiver; and

electrically connecting the RF system receiver to the lead.

25. The method of claim 1 wherein the step of placing a lead near a peripheral nerve that is causing pain includes the step of placing a screening lead near a peripheral nerve that is causing pain; and

wherein the step of electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area includes the step of electrically stimulating the peripheral nerve with the screening lead; and

further comprising the steps of

placing a permanent lead near the peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the permanent lead to cause paresthesia of the painful area.

26. The method of claim 25 wherein the step of placing a permanent lead includes the step of placing a permanent lead across the peripheral nerve that is causing pain.

27. The method of claim 26 wherein the step of placing a permanent lead across the peripheral nerve that is causing pain includes the step of subcutaneously placing a permanent lead across the peripheral nerve that is causing pain.

28. The method of claim 25 wherein the step of placing a permanent lead includes the step of subcutaneously placing a permanent lead near the peripheral nerve that is causing pain.

29. A method of stimulating an occipital nerve to treat occipital neuralgia comprising the steps of:

placing a lead near an occipital nerve that is causing pain;

electrically stimulating the occipital nerve with the lead to cause paresthesia of the painful area.

30. The method of claim 29 wherein the step of placing a lead includes the step of placing a lead across the occipital nerve that is causing pain.

31. The method of claim 30 wherein the step of placing a lead across the occipital nerve that is causing pain includes the step of subcutaneously placing a lead across the occipital nerve that is causing pain.

32. The method of claim 29 wherein the step of placing a lead includes the step of subcutaneously placing a lead near the occipital nerve that is causing pain.

33. The method of claim 29 wherein the step of placing a lead near an occipital nerve that is causing pain includes the step of subcutaneously placing a lead at the level of C1 transversely across the base of the occipital nerve trunk and wherein the step of electrically stimulating the

occipital nerve with the lead to cause paresthesia of the painful area includes the step of electrically stimulating the occipital nerve trunk.

34. A method of stimulating a peripheral nerve to treat pain emanating from the peripheral nerve, the peripheral nerve chosen from a group consisting of a supraorbital nerve , a clunial nerve, an iliolinguinal nerve, a median nerve, an ulnar nerve and a sciatic nerve, the method comprising the steps of:

placing a lead near a peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area.

35. The method of claim 34 wherein the step of placing a lead includes the step of placing a lead across the peripheral nerve that is causing pain.

36. The method of claim 35 wherein the step of step of placing a lead across the peripheral nerve that is causing pain includes the step of subcutaneously placing a lead across the peripheral nerve that is causing pain.

37. The method of claim 34 wherein the step of placing a lead includes the step of subcutaneously placing a lead near the peripheral nerve that is causing pain.

38. The method of claim 34 wherein the step of placing a lead near a peripheral nerve that is causing pain includes the step of placing a screening lead near a peripheral nerve that is causing pain; and

wherein the step of electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area includes the step of electrically stimulating the peripheral nerve with the screening lead to cause paresthesia of the painful area.

39. The method of claim 38 further comprising the steps of:

placing a permanent lead near the peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the permanent lead to cause paresthesia of the painful area.

40. A method of stimulating a peripheral nerve to treat neuralgias emanating from the peripheral nerve, the method comprising the steps of:

placing a lead near a peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area.

41. The method of claim 40 wherein the step of placing a lead includes the step of placing a lead across the peripheral nerve that is causing pain.

42. The method of claim 41 wherein the step of step of placing a lead across the peripheral nerve that is causing pain includes the step of subcutaneously placing a lead across the peripheral nerve that is causing pain.

43. The method of claim 40 wherein the step of placing a lead includes the step of subcutaneously placing a lead near the peripheral nerve that is causing pain.

44. The method of claim 40 wherein the step of placing a lead near a peripheral nerve that is causing pain includes the step of placing a screening lead near a peripheral nerve that is causing pain; and

wherein the step of electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area includes the step of electrically stimulating the peripheral nerve with the screening lead to cause paresthesia of the painful area.

45. The method of claim 44 further comprising the steps of:

placing a permanent lead near the peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the permanent lead to cause paresthesia of the painful area.

46. A method of stimulating a peripheral nerve to treat neuralgias emanating from the peripheral nerve, the neuralgias chosen from a group consisting of post herpetic neuralgia, chronic deafferentation pain, chronic peripheral nerve pain, post craniotomy pain, incisional pain, clunial nerve pain, post herniorrhapy pain, localized low back or other spine pain,

incisional neuroma pain, stump neuroma pain, incisional scar pain, deafferention pain, chronic peripheral nerve pain, sciatic neuralgia, medial neuralgia and ulnar neuralgia , the method comprising the steps of:

placing a lead near a peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area.

47. The method of claim 46 wherein the step of placing a lead includes the step of placing a lead across the peripheral nerve that is causing pain.

48. The method of claim 47 wherein the step of step of placing a lead across the peripheral nerve that is causing pain includes the step of subcutaneously placing a lead across the peripheral nerve that is causing pain.

49. The method of claim 46 wherein the step of placing a lead includes the step of subcutaneously placing a lead near the peripheral nerve that is causing pain.

50. The method of claim 46 wherein the step of placing a lead near a peripheral nerve that is causing pain includes the step of placing a screening lead near a peripheral nerve that is causing pain; and

wherein the step of electrically stimulating the peripheral nerve with the lead to cause paresthesia of the painful area includes the step of electrically stimulating the peripheral nerve with the screening lead to cause paresthesia of the painful area.

51. The method of claim 50 further comprising the steps of:

placing a permanent lead near the peripheral nerve that is causing pain; and

electrically stimulating the peripheral nerve with the permanent lead to cause paresthesia of the painful area.

ABSTRACT of the INVENTION

A method for treating pain by subcutaneous electrical stimulation of a peripheral nerve is disclosed. A lead is placed subcutaneously over a peripheral nerve that is causing pain. The peripheral nerve is electrically stimulated to cause paresthesia. The method encompasses subcutaneous placement of an electrical lead near any peripheral nerve causing pain and subsequent electrical stimulation of the nerve to cause paresthesia. In particular, a method for treating intractable occipital neuralgia using percutaneous peripheral nerve electrostimulation techniques is disclosed.

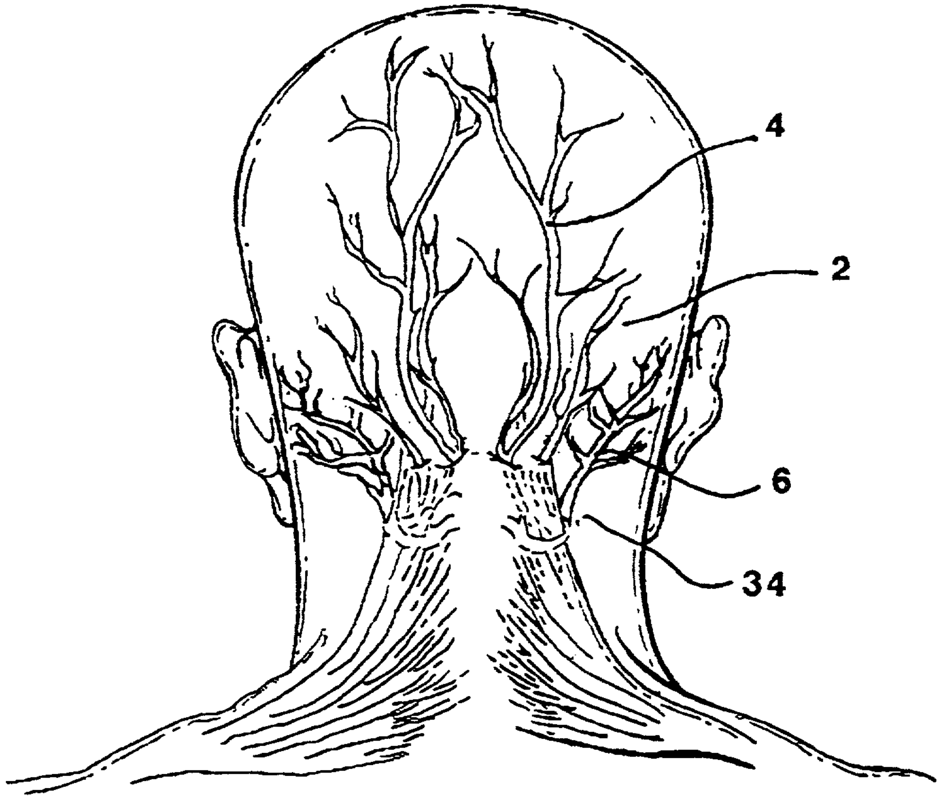


FIG.1

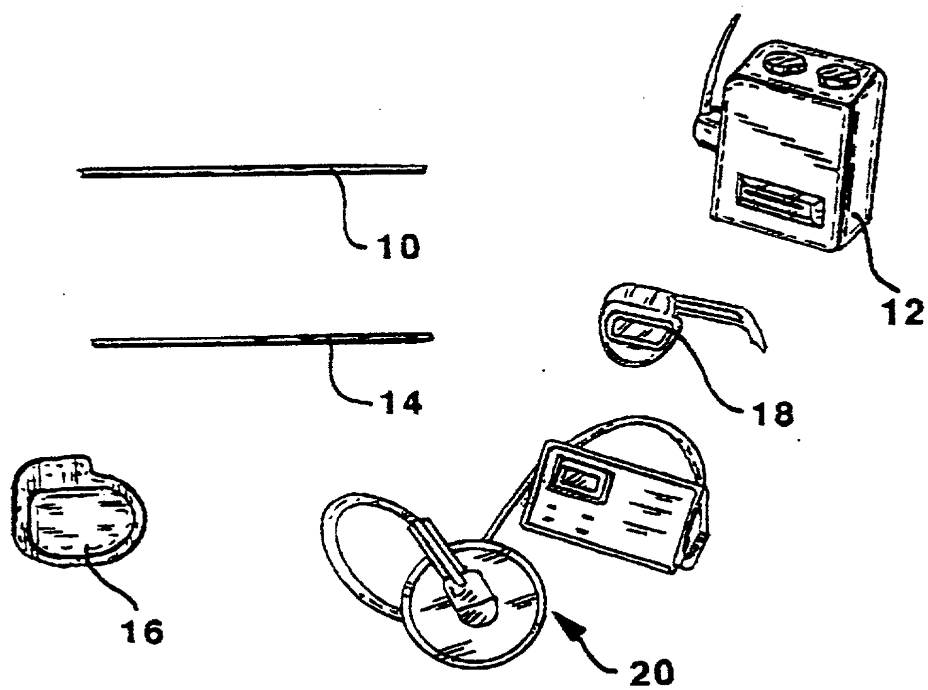


FIG.2

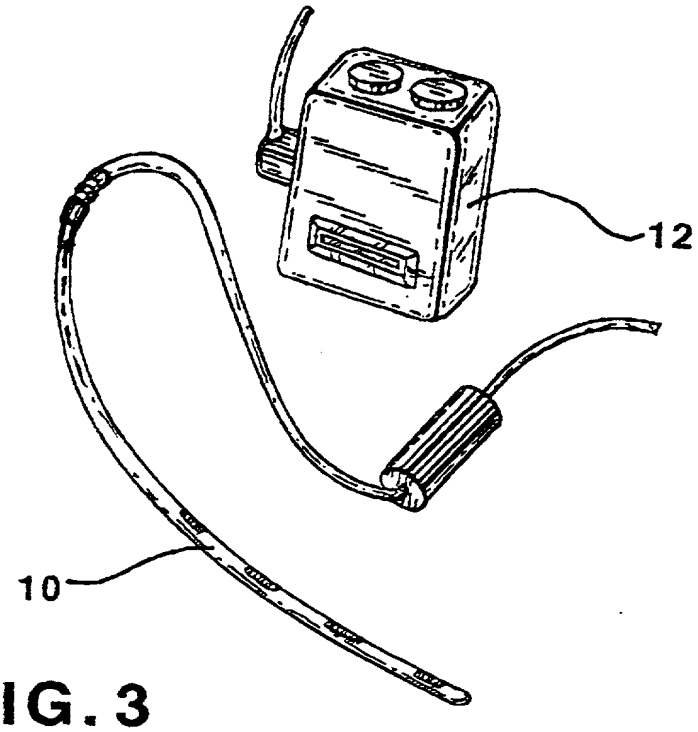


FIG. 3

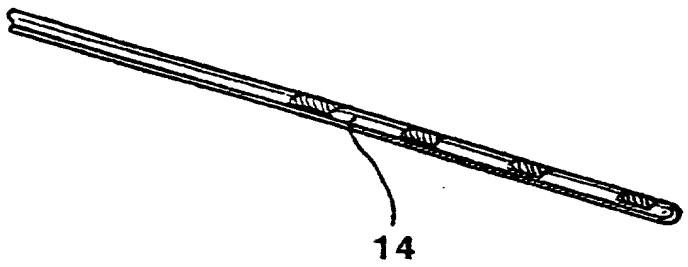


FIG. 4

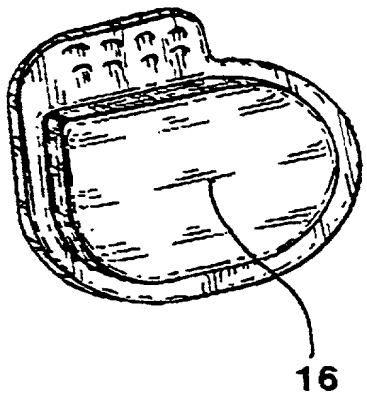
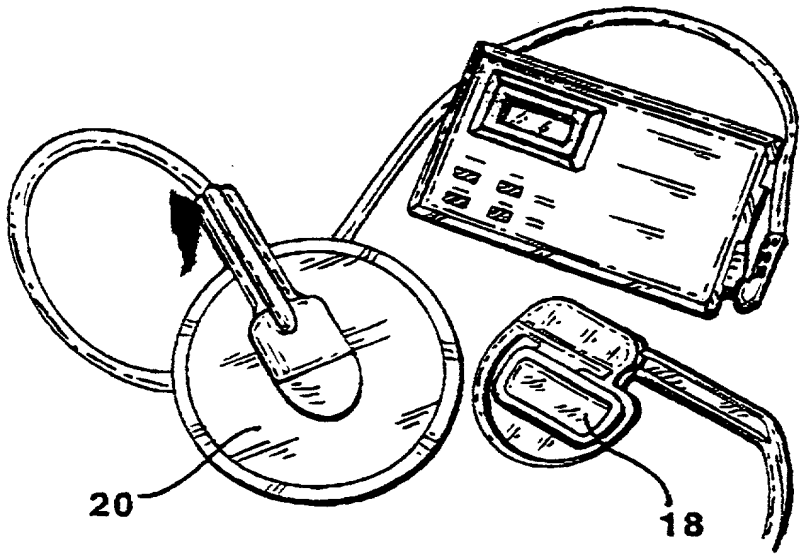


FIG.5



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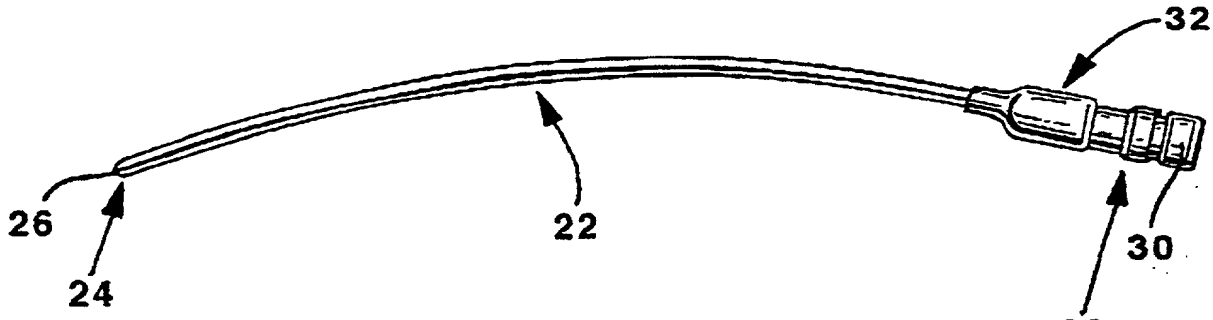


FIG.7

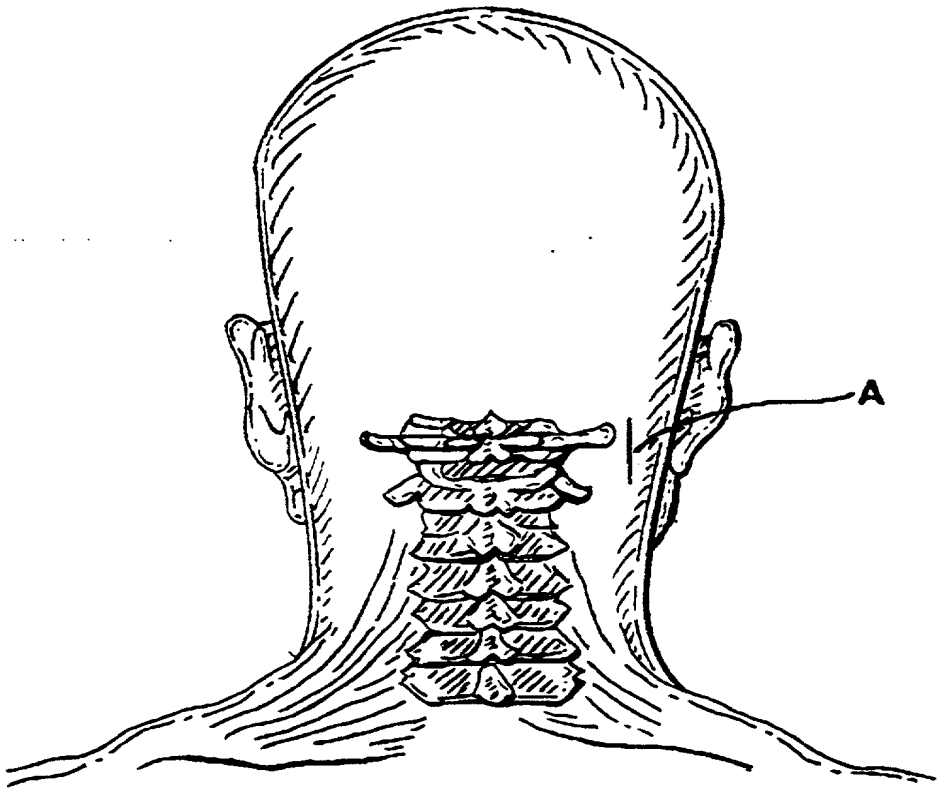
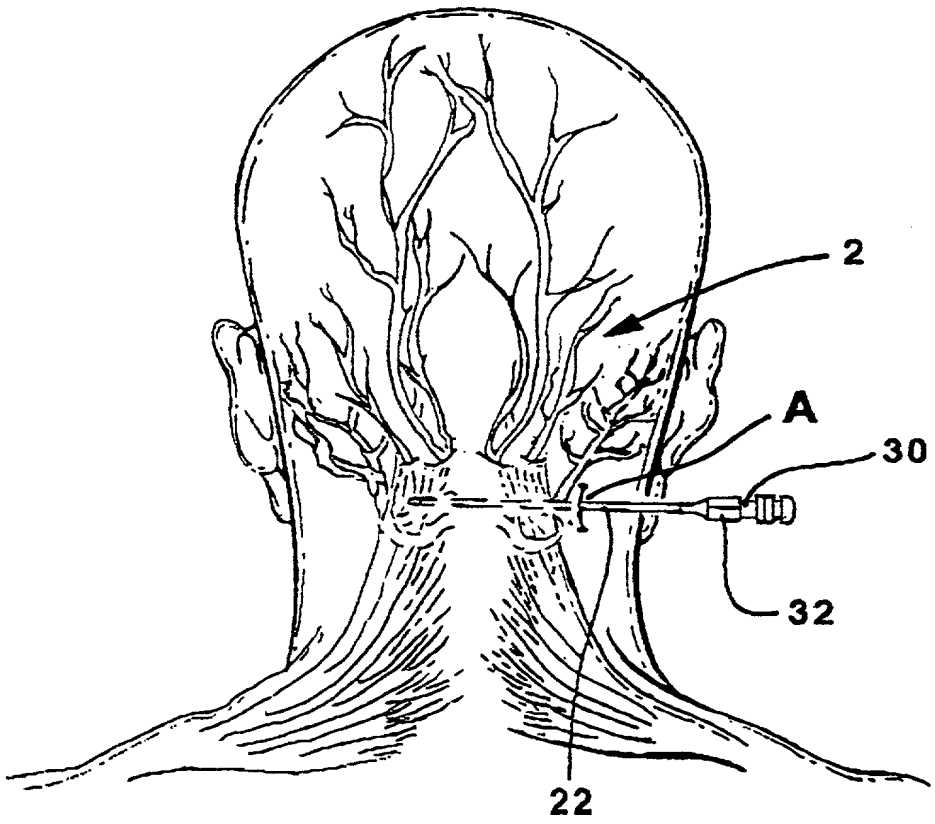


FIG.8



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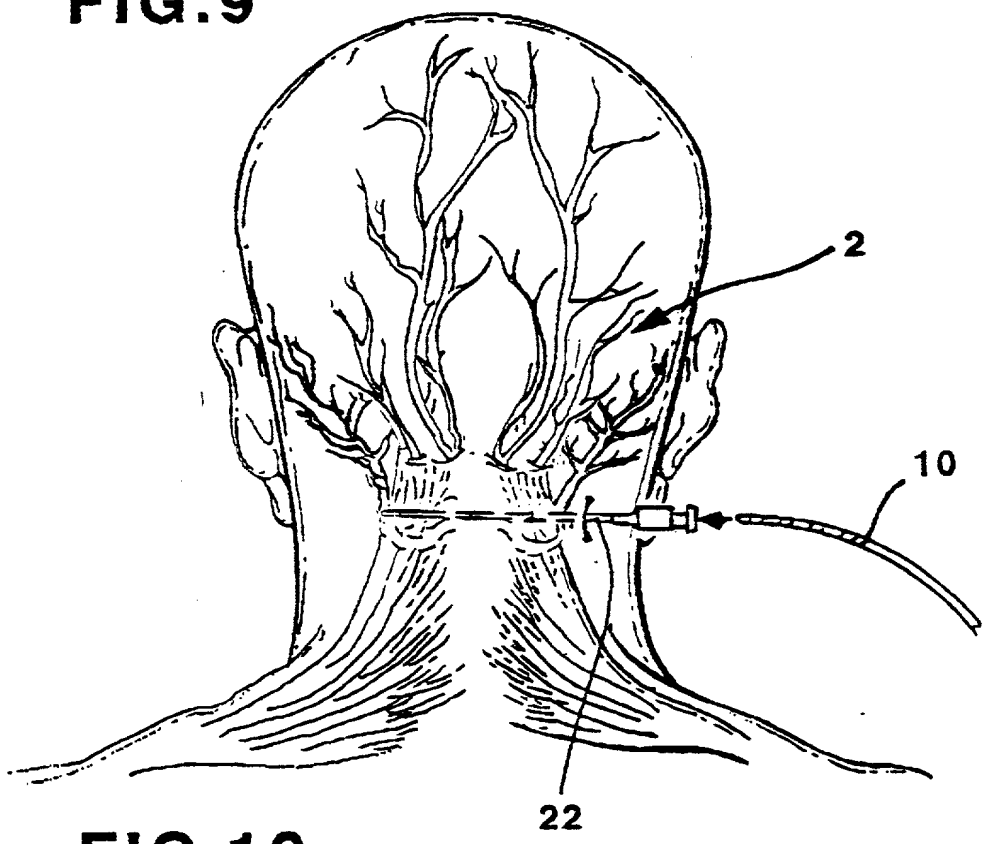

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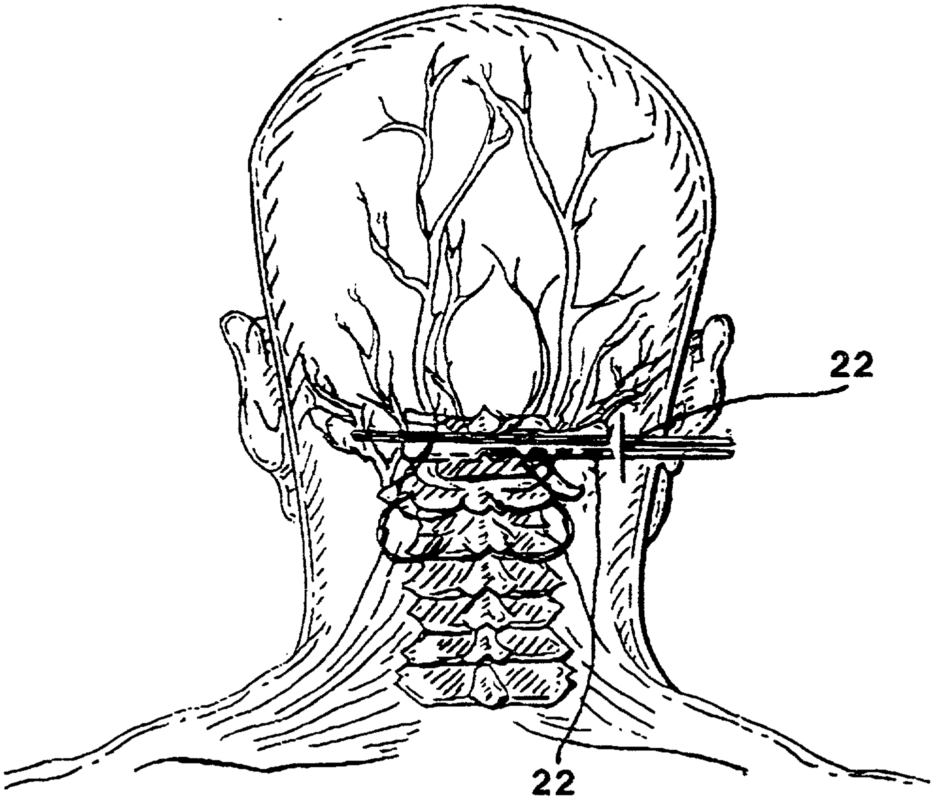

FIG.11

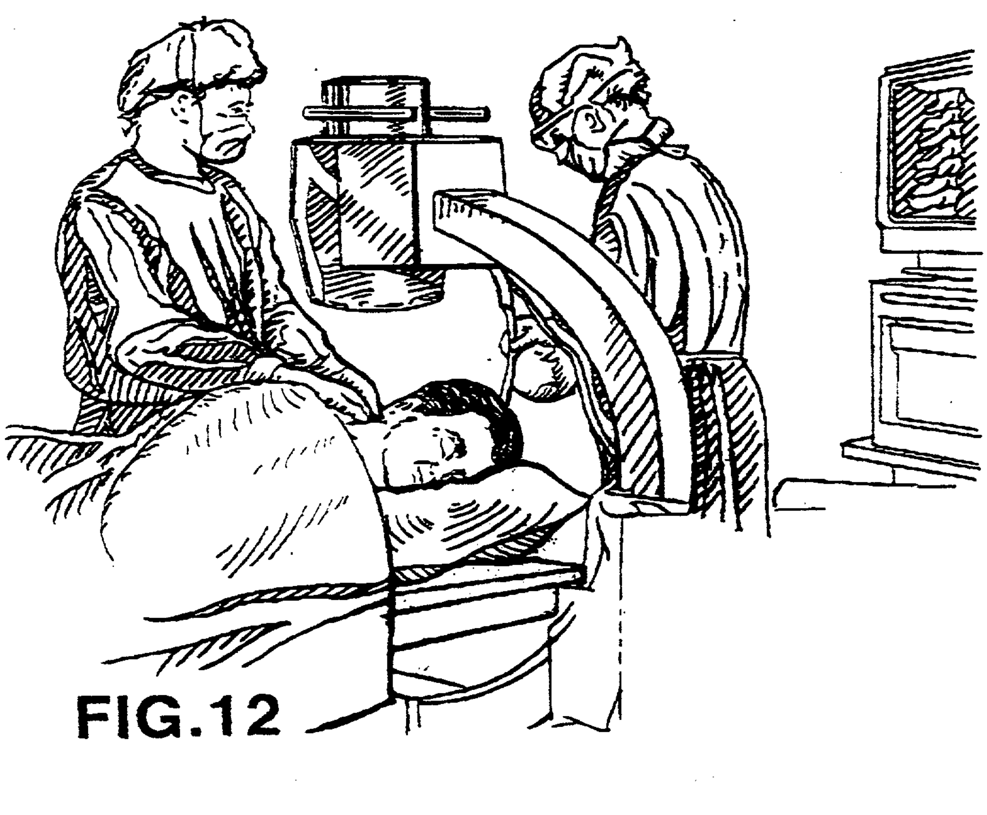

FIG.12

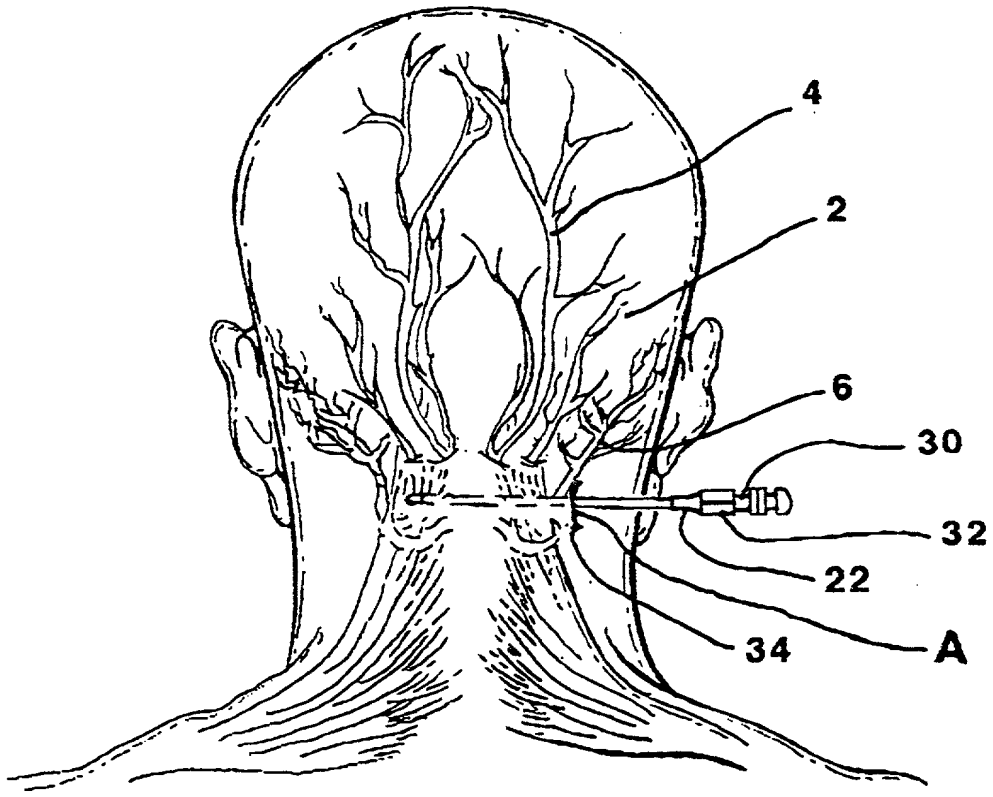

FIG.13

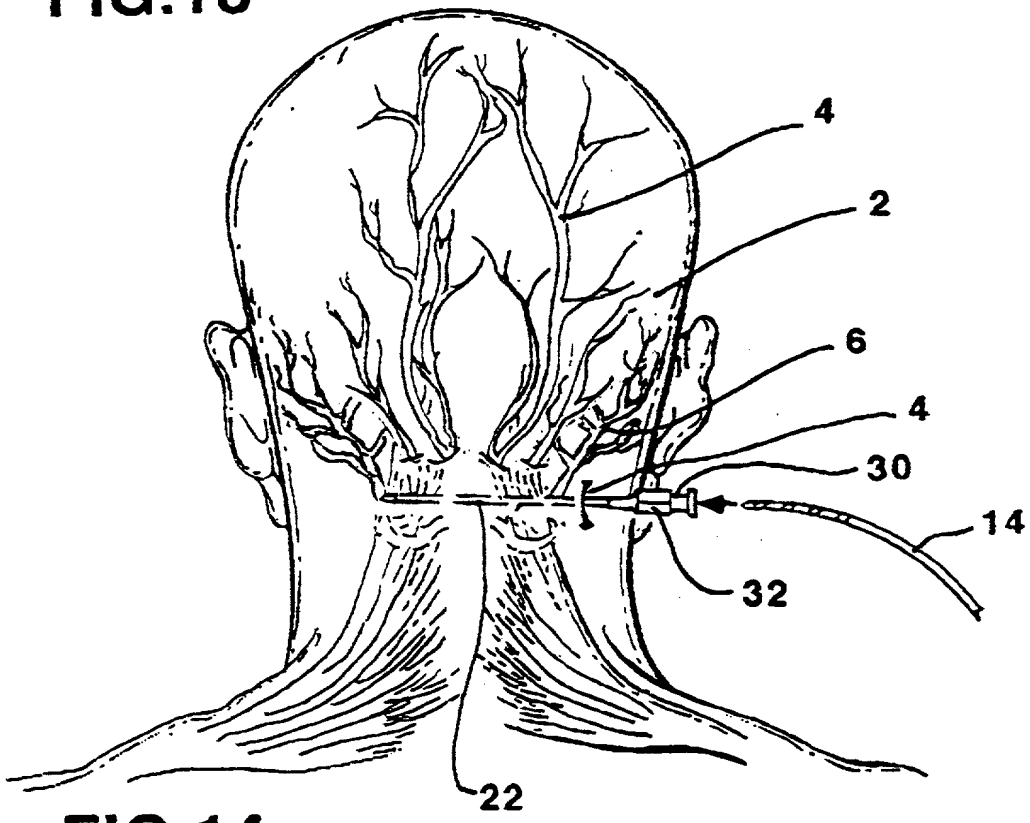

FIG.14

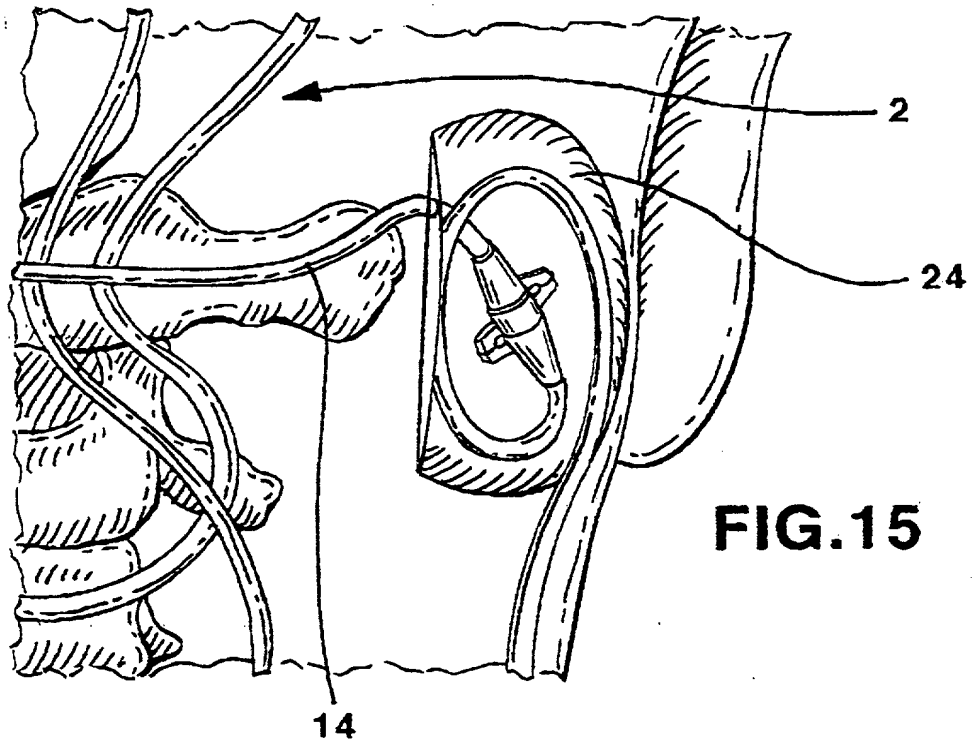
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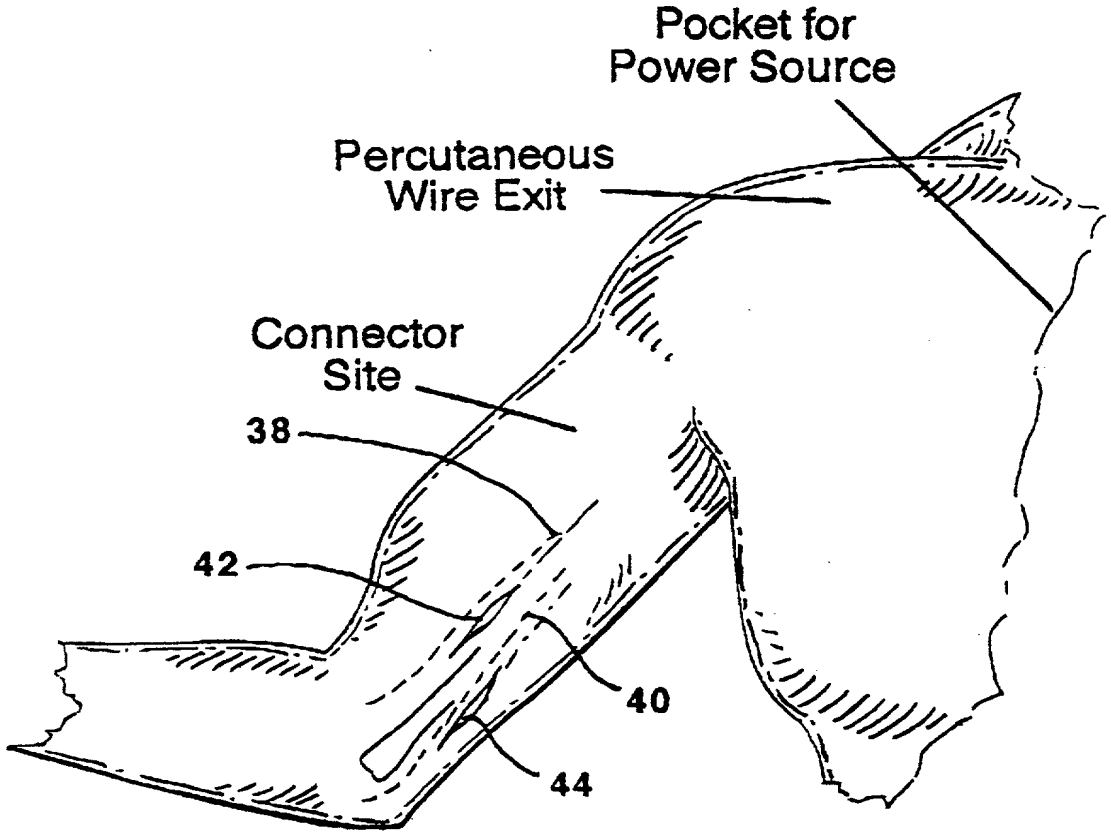
FIG.15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Connector
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42
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44

FIG.16

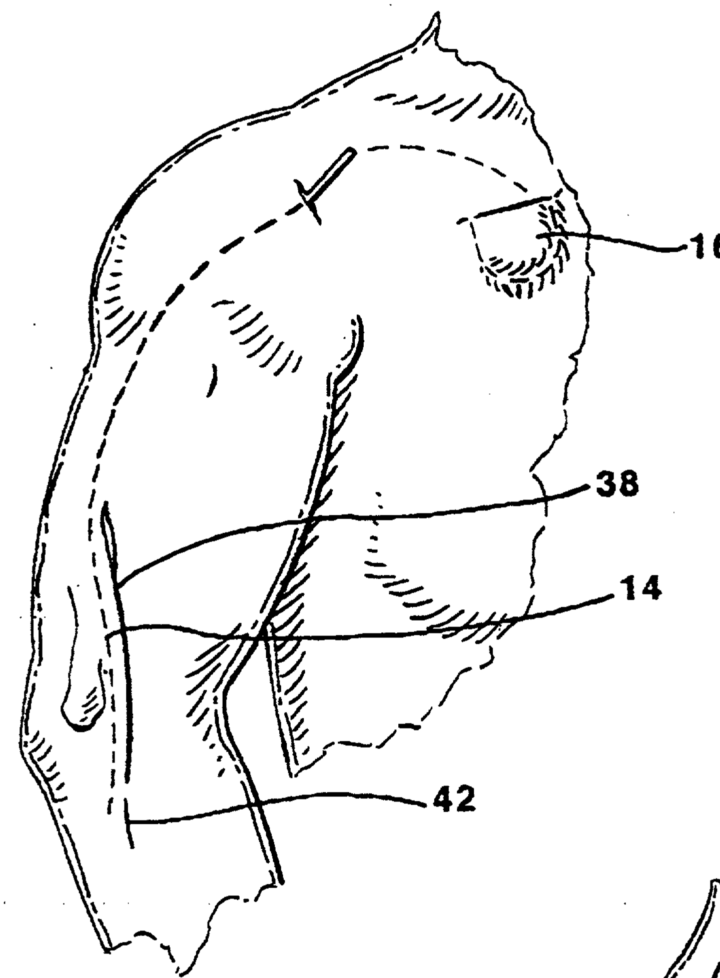

FIG.17

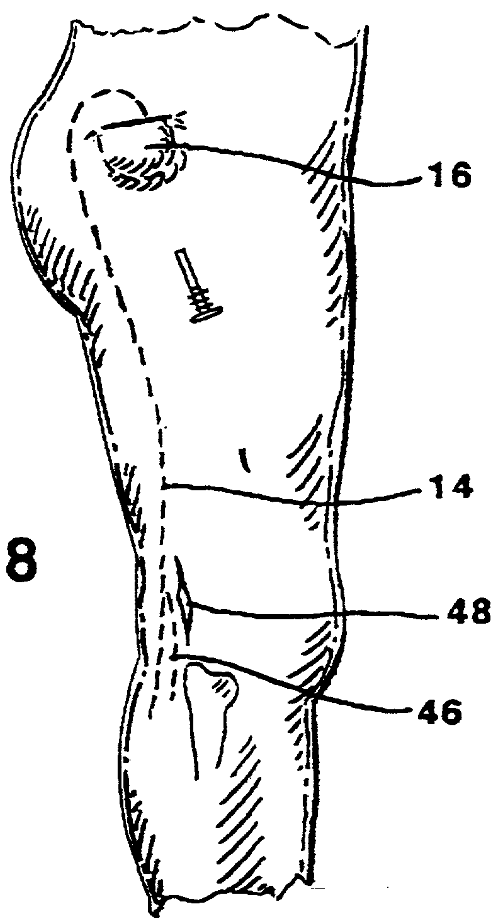

FIG.18

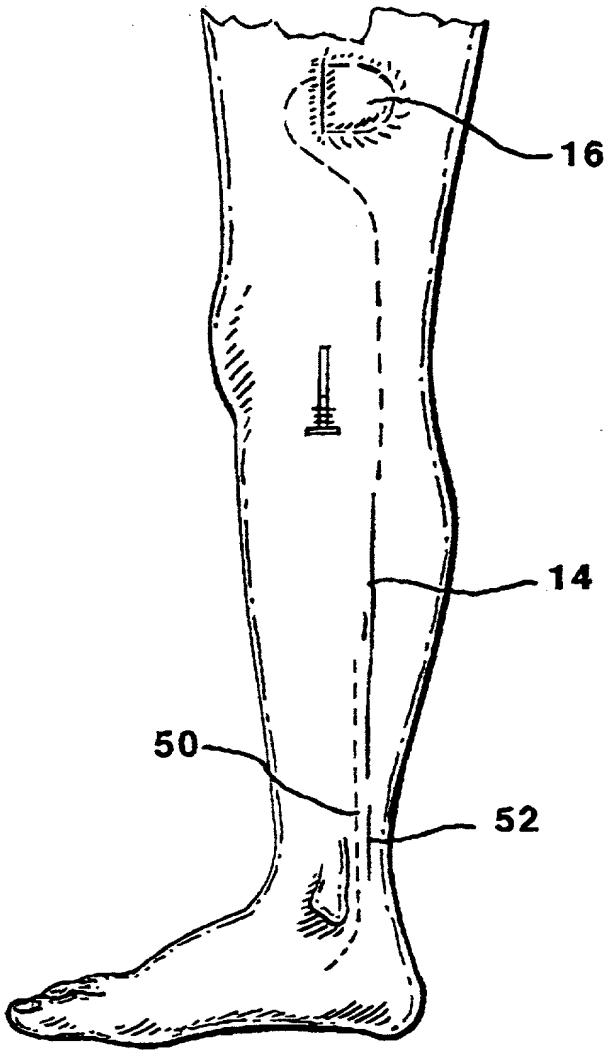

FIG.19

ATTORNEY DOCKET: P-8769

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **PERIPHERAL NERVE STIMULATION METHOD**

The specification of which
a. X is attached hereto
b. __ was filed on _____ as application serial no. _____ and was amended on _____ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. _____ filed _____ and as amended on _____ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).[1]

I hereby claim foreign priority benefits under Title 35, United States Code, §119/365 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

a. _____ no such applications have been filed.
b. X such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC §119

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

I hereby claim the benefit under Title 35, United States Code, §1120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §156(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

---

[1] **§ 1.56 Duty of disclosure; fraud, striking or rejection of applications.**
(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

We hereby claim priority benefits under Title 35, United States Code, §119(e)(1) of any U.S. provisional application listed below:

U.S. APPLICATION NUMBER	DATE OF FILING	STATUS (patented, pending, abandoned)
60/136,690	May 29, 1999	Pending

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Harold R. Patton	Reg. No. 22,157	Reed A. Duthler	Reg. No. 30,626
Michael J. Jaro	Reg. No. 34,472	Eric R. Waldkoetter	Reg. No. 36,713
Daniel W. Latham	Reg. No. 30,401	Girma Wolde-Michael	Reg. No. 36,724
Curtis D. Kinghorn	Reg. No. 33,926	Thomas F. Woods	Reg. No. 36,726
Beth L. McMahon	Reg. No. 41,987		

Please direct all correspondence in this case to: Medtronic, Inc.
7000 Central Avenue N.E,
Minneapolis, Minnesota 55432
Telephone No. (763) 514-3156

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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SIGNATURE OF INVENTOR 201				DATE
202	Full Name of Inventor	FIRST NAME	MIDLE INITIAL	LAST NAME
	Residence & Citizenship	CITY	STATE OR FOREIGN COUNTRY	CITIZENSHIP
	Post Office Address	POST OFFICE ADDRESS	CITY	STATE/ZIP/COUNTRY
SIGNATURE OF INVENTOR 202				DATE

_____ Additional pages for fourth and subsequent inventors attached.

X This Declaration ends with this page.